

**Exhibit (A):
FOIA Request and FOIA Request Confirmation**

**Complaint for Injunctive Relief,
Reed Smith LLP v. Food & Drug Administration
Civil Action No. 21-2387**



Driving progress
through partnership

Rachael G. Pontikes

Direct Phone: +1 312 207 2857

Email: rpontikes@reedsmith.com

Reed Smith LLP
10 South Wacker Drive
Chicago, IL 60606-7507
+1 312 207 1000
Fax +1 312 207 6400
reedsmith.com

July 28, 2021

Via Online Access Portal

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

RE: Freedom of Information Act Request

To Whom It May Concern:

We submit the following Freedom of Information Act (“FOIA”) request to the Food and Drug Administration (“FDA”).

A. Requestor’s name, address, and telephone number.

Rachael G. Pontikes
Reed Smith LLP
10 South Wacker Drive, 40th Floor
Chicago, IL 60606
(312) 207-2857

B. A description of the records being sought. The records should be identified as specifically as possible. A request for specific records that are releasable to the public can be processed much more quickly than a request for “all information” on a particular subject. Also fees for a more specific and limited request will generally be less.

We request the following records:

- All communications* between FDA (including, but not limited to, FDA’s Center for Drug Evaluation and Research (“CDER”)) and the Pharmacy Compounding Advisory Committee from January 1, 2014, to the present regarding the following subjects:
 - Nicotinamide adenine dinucleotide; or

* For purposes of this FOIA request, the term “communications” includes, but is not limited to, e-mail messages, letters, and memoranda, as well as calendar invitations and notations.

Food and Drug Administration
July 28, 2021
Page 2

ReedSmith

- The criteria used to determine whether a bulk drug substance should appear on the list established pursuant to section 503A(b)(1)(A)(i)(III) of the Federal Food, Drug, and Cosmetic Act, including, but not limited to, any criteria not reflected in a codified regulation.
- All communications regarding nicotinamide adenine dinucleotide between FDA (including, but not limited to, FDA's CDER) and persons or entities receiving federal grant funding (including, but not limited to, the University of Maryland Center of Excellence in Regulatory Science and Innovation) from January 1, 2014, to the present.

C. A statement concerning willingness to pay fees, including any limitations.

We will pay all fees associated with this request. If the agency estimates that those fees will exceed \$1,000.00, please contact me before proceeding further.

Very truly yours,

/s/ Rachael G. Pontikes

Rachael G. Pontikes
For Reed Smith LLP



FOIA Request Confirmation

Confirmation Number: FDA2175848

Requester:

General

| | |
|----------------------------|------------------------|
| Description of Requester: | Commercial user |
| Max Amount Willing to Pay: | \$1,000 |

Organization

| | | | |
|--------------------|--------------------------------|--------------|--|
| Organization Name: | Reed Smith LLP | | |
| Primary Phone: | 312-207-2857 | Other Phone: | |
| Email: | rpontikes@reedsmith.com | | |

Mailing Address

| | |
|------------|------------------------------|
| Address 1: | 10 South Wacker Drive |
| Address 2: | 40th Floor |
| City: | Chicago |
| State: | IL |
| Zip Code: | 60606 |

Billing Address

| | |
|------------|------------------------------|
| Address 1: | 10 South Wacker Drive |
| Address 2: | 40th Floor |
| City: | Chicago |
| State: | IL |
| Zip Code: | 60606 |

Details

| | | | |
|----------------------|--|--------------------|---|
| Requester Name: | Rachael G. Pontikes | | |
| Requester File #: | | Request Letter: | FOIA Request (July 28, 2021).pdf |
| Requested Date From: | 01/01/2014 | Requested Date To: | 07/28/2021 |
| Subject of Request: | We request the following records: (1) all communications* between FDA (including, but not limited to, FDA's Center for Drug Evaluation and Research | | |

Waiver of Fees

| | |
|----------------|--|
| Justification: | |
|----------------|--|

Expedited Processing

| | |
|----------------|--|
| Reason: | |
| Justification: | |

[Print](#) [Create Another Request](#) [Close](#)

Within 10 business days of the submission of your online request, you will receive by electronic mail an FOIA Control Number. If you need to communicate with FDA regarding your request, please refer to this Control Number. Requests received after 4:00 P.M. E.S.T. will be considered to have been received on the following business day.

If your informational needs change, and you need to cancel your request, please contact the Division of Freedom of Information by telephone, mail, or fax. Please include your control number in the correspondence. For contact information, please see [FDA's FOIA page](#).